UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES, Plaintiffs, v. BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, BIOMET MANUFACTURING, LLC f/k/a BIOMET MANUFACTURING CORP., Defendants.	Case No. 4:13-cv-00800-SRC

DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW AND MEMORANDUM IN SUPPORT

Defendants move the Court under Rule 50 to grant them judgment as a matter of law ("JMOL") on all of Plaintiffs' remaining claims for compensatory damages based on strict-liability design defect and negligent design, and on the derivative loss-of-consortium claim. Plaintiffs failed to offer sufficient evidence to permit a jury to find in their favor on the elements of design defect and causation.

Defendants also move the Court for JMOL on Plaintiffs' claim for punitive damages, both because Plaintiffs' claims for compensatory damages fail and because Plaintiffs have failed to present clear and convincing evidence that Biomet's conduct showed an evil motive or reckless indifference to the rights of others.

FACTS

The following facts about the design and performance of the M2a are undisputed:

1. No Plaintiffs' expert witness offered *any* testimony criticizing the specific design or the performance of the M2a Magnum. Instead, they attacked the entire class of "second

generation" metal-on-metal hip replacement devices and criticized Biomet's decision to design and sell a second-generation total hip arthroplasty ("THA") device that used a metal-on-metal articulating surface.

2. At the time Mrs. Bayes received her M2a Magnum implant in 2008, the clinical performance data demonstrated an overwhelmingly successful product:

- The National MAUDE Database included 2 complaints out of 25,000 devices places for a .008% revision rate, or 99.99% success rate;
- Biomet' internal complaint files included 14 complaints out of 25,000 devices placed for a .056% complaint rate, or a 99.94 % success rate.

Oct. 16, 2020 Tr. 229:14–1, 230:7–24; Tr. Ex. AGA, p.7.

3. By 2016, 12 years after the M2a Magnum came to market and eight years after Mrs. Bayes received her implant, the revision rate was a cumulative 4.63%, for a success rate of 95.37%. This rate is vastly better than the "second generation" metal-on-metal class of products as a whole, which had an 88.9% success rate in the Australian device registry, and an 88.25% success rate in the New Zealand registry. Oct. 16, 2020 Tr. 237:3-239:24; Tr. Ex. AGA, at 22.

4. Although Plaintiffs' experts proposed a metal-on-polyethylene design as a "reasonable alternative design," at 12 years after introduction, the M2a Magnum's success rate was as good as metal-on-poly products:

M2a Magnum	95.37%
Australian Registry all MOP	96.61%
New Zealand Registry all MOP	95.75%

Oct. 16, 2020 Tr. 237:3-239:24. None of Plaintiffs' experts addressed Biomet's performance data or in any way assessed the M2a Magnum revision rates or relative performance compared to metal-on-polyethylene designs.

5. Both parties' experts agreed that a high inclination (abduction) angle (over approximately 60 degrees) of an acetabular cup increases the wear rate of any bearing surface. *See* Oct. 15, 2020 Tr. 214:12-17 (Lux); Oct. 8, 2020 Tr. 178:18–23 (Kantor); Oct. 16, 2020 Tr. 47:9–25, 62:5–19 (S. Kurtz).

6. Both parties' witnesses' agreed that Mrs. Bayes's left acetabular cup was at a high angle of abduction at the time of revision. At revision, Plaintiff's **left** acetabular cup was positioned at 60 degrees or more of abduction.[1] Her left cup experienced metallosis, while her right cup (which did not feature high inclination) did not. Dr. Lux's surgical observations at the time of the **left** hip revision included "extensive metallosis in the space between the abductor musculature and the undersurface of the fascia lata and gluteus." Trial Ex. JW, at 42–43. In contrast, at the time of Plaintiff's **right** hip revision in 2014, Dr. Ryan Nunley observed "no overwhelming signs of metallosis, [and] there was no signs of metal staining." Trial Ex. JE-1, at 128.

ARGUMENT

I. Plaintiffs' Claims for Compensatory Damages Fail as a Matter of Law

A. The Standard for Judgment as a Matter of Law

Under Federal Rule of Civil Procedure 50(a)(2), a party is entitled to judgment as a matter of law "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue." Fed. R. Civ. P. 50(a)(1). The inquiry is the same as for a summary judgment: '[W]hether the evidence presents a sufficient disagreement to require submission to a jury or

[1] *See* Oct. 15, 2020 Tr. 209:17-20. (60 degrees abduction at time of revision); Trial Exhibit JT, at 2, 11/12/2010 J. Martin Note ("about 60-65 degrees open" in November 2010); Oct. 16, 2020 Tr. 59:19–60:8 ("between 62 and 64 degrees of inclination").

whether it is so one-sided that one party must prevail as a matter of law.'" *Linden v. CNH America, LLC*, 673 F.3d 829, 834 (8th Cir. 2012) (quoting *Kinserlow v. CMI Corp.*, 217 F.3d 1021, 1025 (8th Cir. 2000)).

B. Plaintiffs failed to offer sufficient evidence to permit a reasonable jury to conclude that the M2a Magnum's design was defective and unreasonably dangerous or that Biomet was negligent in designing the M2a Magnum.

Plaintiffs did not introduce evidence that the M2a Magnum had a design defect to support their strict liability design defect or negligent design defect claims. A product has a design defect if it creates an unreasonable risk of danger to the consumer or user when put to the normal use. *Linegar v. Armour of America, Inc.*, 909 F.2d 1150, 1153 (8th Cir. 1990); *Glass v. Allis-Chalmers Corp.*, 789 F.2d 612, 613 (8th Cir. 1986) (requiring proof of "the existence of the claimed defects"); MAI 25.09 Product Liability – Negligent Manufacture, Design, or Failure to Warn (requiring proof that the product was in a "defective condition unreasonably dangerous").

Evidence that a general class of products is prone to a specific risk cannot by itself establish a defect in a particular product. *See Glass*, 789 F.2d at 614. Thus, as this Court has held,[2] the failure of other metal-on-metal devices cannot be used to show that the design of the M2a Magnum is unreasonably dangerous. Oct. 8, 2020 Tr. 20:19-22. Here, however, such generic evidence is all Plaintiffs have offered. This evidence is insufficient under Missouri law. *See Glass*, 789 F.2d at 614 (holding evidence that "combines in general" can "catch fire for various reasons" was not enough to generate a submissible claim on design defect).

Plaintiffs introduced no evidence that the M2a Magnum's design was defective and unreasonably dangerous. The majority of Plaintiffs' experts, including Dr. George Kantor, Dr.

[2] *See* Oct. 8, 2020 Trial Tr. 20:19-22 ("[T]he plaintiffs may not offer evidence of the failure of these other devices to show that the design of the M2a-Magnum is unreasonably dangerous."); *id.* at 16:20–22 (finding "plaintiffs have not shown that these other products are substantially similar to the M2a-Magnum").

Paul Lux, and Dr. Francis Gannon, expressly offered no opinion that the M2a Magnum had a design defect. *See* Oct. 15, 2020 Tr. 175:9-11, 176:9-11 (Lux); Oct. 14, 2020 Tr. 294:5-22, 305:11-19 (Gannon); Oct. 8, 2020 Tr. 136:7-9, 141:4-11, 142:7-17, 143:13–19, 145:4–6 (Kantor); *see also* Doc. 21-5, MDL Expert Order, at 38–39 (precluding Kantor from testifying about any specific design defects associated with the M2a Magnum).

Plaintiffs' only remaining retained expert — Mari Truman — did not testify that there was any design defect specific to the M2a Magnum. Truman has never performed any testing on frictional torque for the M2a Magnum and testified that the M2a Magnum's clearance was "the best you could probably do for a metal-on-metal hip." *See* Oct. 14, 2020 Tr. 141:12-17 (clearance); *id.* 143:3-13 (frictional torque). Truman also testified that cobalt chrome—the alloy used for the M2a Magnum — is the "workhorse material for a lot of orthopedic devices" and is a very good biocompatible material. *Id.* at 153:25-154:6. She explained that revisions, standing alone, does not necessarily mean that there is anything wrong with the device design. *Id.* at 154:14–19. Truman conceded that Biomet complied with the accepted industry standards for testing. *Id.* 136:18–22. Finally, Truman agreed that Mrs. Bayes's right M2a Magnum, the only device preserved for testing, exhibited a wear rate consistent with a well-functioning metal-on-metal hip and consistent with Biomet's simulator testing. *See id.* at 177:10-20, 179:19-25, 180:15-20.

No evidence identifies a specific design defect in the M2a Magnum, and the only evidence admitted at trial demonstrates that other metal-on-metal devices had higher revision rates than the M2a Magnum. Oct. 16, 2020 Tr. 229:14–1, 230:7–24, 237:3-239:24; Tr. Ex. AGA, pp. 7, 22. Absent evidence of an actual design defect in the M2a Magnum, Plaintiffs' design defect and negligent design claims fail as a matter of law. Proof of a design defect cannot rest on

"pure speculation and conjecture." *See Braun v. Gen. Motors Corp.*, 579 S.W.2d 766, 770 (Mo. App. E.D. 1979) (holding highly generic expert testimony regarding general laws of physics was insufficient to create jury question on whether specific product was unreasonably dangerous). The Court should grant Biomet JMOL on those claims.

C. Plaintiffs failed to offer sufficient evidence to create a jury issue on the element of causation.

Medical causation – establishing a causal link between a product defect and a plaintiff's injuries – is an essential element in all product liability cases.[3] Expert testimony is necessary to establish medical causation because a jury would "not possess the experience or knowledge of the subject matter sufficient to enable them to reach an intelligent opinion without help." *Siebern v Mo-Illinois Tractor & Equipment Co.*, 711 S.W.2d 935, 939 (Mo. Ct. App. 1986) (expert testimony necessary to prove "defectiveness" for complex machine). Absent expert testimony on medical causation, a product liability claim faces dismissal. *See, e.g., Looney v. Zimmer, Inc.* No. 03-0647-CV-W-FJG, 2004 WL 1918720, at *5 (W.D. Mo. Aug. 19, 2004) (dismissing claim of defective knee implant for lack of expert testimony on causation.).

Here, Plaintiffs needed to offer expert testimony that some claimed defect in Mrs. Bayes's M2a Magnum *caused* her claimed injuries and the need for her revision surgeries. They failed to do so, and the Court should grant Biomet JMOL on their design defect and negligent design claims. The expert testimony Plaintiffs introduced at trial offered no basis for a causal link between any purported design defect in the M2a Magnum and Mrs. Bayes' claimed injuries, so their claims should be dismissed.

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[3] Mo. Rev. Stat. § 537.760(3)(a) (a design or manufacturing defect claim requires that the plaintiff was "damaged as a direct result" of the defect); *Poage v. Crane Co.*, 523 S.W.3d 496, 508 (Mo. App. E.D. 2017) (negligence claims require medical causation).

1. Plaintiffs' medical experts failed to offer proper, reliable differential diagnoses that would permit a jury to infer causation.

Plaintiffs' medical experts (Kantor and Lux) failed to adequately account for or rule out the obvious alternative explanations that they and Mrs. Bayes's other treating physicians acknowledge, including the positioning of the left acetabular cup. *See* Oct. 8, 2020 Tr. 192:2–193:17,[4] 195:25-196:3 (Kantor); 215:11-14 (Lux). This makes their testimony fundamentally flawed, unreliable, and insufficient as a matter of law to establish specific medical causation.

Kantor neither considered nor ruled out the possibility that two years of excessive wear and edge loading due to a vertical cup could have caused Mrs. Bayes's left hip metallosis and related complications. *See* Oct. 8, 2020 Tr. 195:16-196:3. That is not enough to generate a jury question on the issue of medical causation under Missouri law. *See, Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852, 862–63 (Mo. banc. 1993) ("The 'but for' causation test provides that 'the defendant's conduct is a cause' of the event if the event *would not have occurred 'but for' that conduct*." (emphasis added) (citing Prosser and Keeton on Torts, § 41 at 266 (5th ed. 1984)). *Cf. Redd v. DePuy Orthopaedics*, 700 F. App'x 551, 554 (8th Cir. 2017) (per curiam) ("Although [plaintiff] is correct that an expert need not rule out all possible causes of an injury, an expert nonetheless should 'adequately account[] for obvious alternative explanations.'"). Here, Kantor's opinions do not account for other, independent causes of Mrs. Bayes's left hip implant failure, such as the vertical position of the cup, so his opinions cannot support a jury verdict in Plaintiffs' favor on causation. *See Callaham*, 863 S.W.2d at 862.

Lux likewise did not rule out the positioning of Mrs. Bayes' left cup as the cause of her injuries. Lux admitted that he could not rule out the cup positioning as the cause of Mrs. Bayes

[4] Dr. Kantor testified that he had looked at x-rays from Mrs. Bayes' left hip taken over the first six months of her implant, and possibly others, but could not be sure that he looked at any x-rays from 2010 through revision. *See* 10/8/2020 Tr. 192:2–193:17

left hip problems. Oct. 15, 2020 Tr. 192:6–18. Lux's inability to rule out positioning as a cause renders his causation opinion insufficient to support the element of causation. *See Callahan*, 863 S.W.2d at 863; *Redd*, 700 Fed. Appx. at 554.

Lux's and Kantor's testimony did not support a causal link between the M2a Magnum and Mrs. Bayes's right revision surgery. Lux agreed that the right revision showed no overwhelming signs of metallosis, no signs of metal staining, and no obvious signs of metallosis at the trunnion. Oct. 15, 2020 Tr. 196:9-19.[5] He did not know that Mrs. Bayes's metal ion levels had been steadily decreasing over time, and further admitted that orthopedic surgeons "really don't know the significance" of metal ion testing anyway. *See id.* at 74:12–14, 196:20-24. Further, Lux admitted that Mrs. Bayes had a very different experience in her right hip than in her left hip, including no evidence of metallosis and no build-up of fluids during her right revision surgery. *See id.* 216:17–24. Similarly, Kantor could not identify how any defects in the M2a Magnum caused Plaintiff's right hip revision surgery, and instead testified that Mrs. Bayes's right hip was removed before any changes from metallosis occurred. *See* Oct. 8, 2020 Tr. 119:1–7, 203:6–15. And both parties' experts agree that the explanted right prosthesis demonstrated very low wear. *See* Oct. 14, 2020 Tr. 177:10-20, 179:19-25, 180:15-20.

Even assuming Mrs. Bayes developed metal injury, Lux and Kantor failed completely to consider alternative factors. Not only did they fail to consider the potential role of other metal implants present in Plaintiff's body, they failed to consider the positioning of the cup. Nunley observed "excessive anteversion" to the right acetabular cup during the revision procedure, at "close to 45 degrees." Trial Ex. JE-1, at 128. Nunley testified that he "intraoperatively assessed it, and didn't like the position," so he changed it at the revision surgery. *See* Oct. 9, 2020 Tr.

[5] Dr. Nunley testified that these surgical findings did not give him any concern. *See* Oct. 13, 2020 Tr. 218:12–24.

83:19–84:8. Yet, Kantor and Lux did not consider, let alone rule out, the role that such positioning would have had on Mrs. Bayes's right hip. In sum, neither of the supposed differential diagnoses by Plaintiffs' experts Kantor and Lux are sufficient to allow a jury to conclude that Mrs. Bayes's M2a Magnum implant caused her injuries, and Biomet is therefore entitled to JMOL. *See Callahan*, 863 S.W.2d at 863; *Redd*, 700 Fed. Appx. at 554.

2. Plaintiffs' design expert did not raise a jury question that a specific design defect in the M2a Magnum *caused* Mrs. Bayes's injuries.

Even assuming for the sake of argument that Plaintiffs' medical experts had produced sufficient evidence to permit the jury to conclude that Mrs. Bayes' M2a Magnum implant caused her injuries, Defendants are nevertheless entitled to JMOL because Plaintiffs offered no expert testimony that some defect in the design of the M2a Magnum caused those injuries, a critical link in Plaintiffs' chain of causation. *See, e.g.*, Mo. Rev. Stat. § 537.760(3)(a) (a design or manufacturing defect claim requires that the plaintiff was "damaged as a direct result" of the defect); *Coterel*, 827 F.3d at 808 (same).

Plaintiffs' evidence failed to link ***any*** M2a Magnum design choice, much less a defective design choice, to Mrs. Bayes's claimed injuries. The only expert Plaintiffs offered who reviewed the M2a Magnum's design files, Mari Truman, did not link her criticisms of the M2a Magnum's design to Mrs. Bayes's claimed injuries.[6] On the contrary, she admitted that a patient's surgical outcome depends on various factors, including design factors, patient factors, and surgical factors. *See* Oct. 14, 2020 Tr. 155:21-24. Truman, Plaintiffs' design expert, admitted that the wear rate of the right hip was quite low, *see id.* at 172:24-173:1, and her measured wear rate fell within the 1996 Consensus Statement's range for well-functioning metal-on-metal hips, and

[6] Mari Truman was precluded from opining on medical causation. *See* Doc. 251, at 11 ("The Court grants Biomet's motion to preclude Truman from opining on medical causation.").

within Biomet's simulator testing results. *See id.* at 177:10-20, 179:19-25, 180:15-20. In light of these findings, Truman's unsupported opinion that the metal-on-metal bearing (as opposed to the positioning of the acetabular cups) caused Mrs. Bayes's revision surgeries and claimed injuries is insufficient to support a claim that some unidentified defect in the product design causes Plaintiffs' injuries. Truman failed to create a jury question as to either specific product defect or causation.

D. Mr. Bayes's derivative loss of consortium claim fails as a matter of law.

A claim for loss of consortium is wholly derivative of the injured spouse's claim. *Wright v. Barr*, 62 S.W.3d 509, 537 (Mo. App. 2001). "Thus, *it is axiomatic that one spouse may not be awarded damages for loss of consortium if the other is not injured,* although one spouse suffering injuries does not automatically entitle the other to damages for loss of consortium." *Id.* (emphasis added). Plaintiff Philip Bayes's loss of consortium claim is derivative of his wife Mrs. Bayes's claims. Because Plaintiffs cannot establish that Biomet is liable to Mrs. Bayes for any injuries, Mr. Bayes's loss of consortium claim necessarily fails as a matter of law. *See id.*

II. Plaintiffs' Claim for Punitive Damages Fails as a Matter of Law.

The Court should grant Defendants JMOL on Plaintiffs' claim for punitive damages. First, a claim for punitive damages depends on an actual and substantial award of compensatory damages. *See Harris v. Jungerman*, 560 S.W.3d 549, 555 (Mo. App. 2018) ("A claim for punitive damages is not an independent cause of action; rather it is incidental to the underlying cause of action."). Because Plaintiffs' underlying product liability claims fail, as discussed above, those claims cannot support a claim for punitive damages.

But even assuming for the sake of argument that Plaintiffs had established a prima facie case for design defect or negligent design, Biomet is nevertheless entitled to JMOL on punitive

damages because Plaintiffs have failed as a matter of law to meet the high threshold that Missouri law[7] imposes for the submission of a punitive damages claim to a jury.[8]

A. Plaintiffs cannot meet the high standard for punitive damages.

Missouri law sets a high standard for punitive damages, and "many cases have been reversed because of a punitive damages award." *Jone v. Coleman Corp.*, 183 S.W.3d 600, 610 (Mo. App. 2005); *see also Angotti v. Celotex Corp.*, 812 S.W.2d 742, 746 (Mo. 1996). To permit a punitive damage award for a product liability claim, a plaintiff must present evidence that "the defendant placed an unreasonably dangerous product into the stream of commerce with actual knowledge of the defect." *Jone*, 183 S.W.3d at 610. Punitive damages may be awarded in a negligence action only if the defendant knew or had reason to know a high degree of probability existed that the action would result in injury. *Stojkovic v. Weller*, 802 S.W.2d 152, 155 (Mo. banc 1991), *overruled on other grounds by Rodriguez v. Suzuki Motor Corp.*, 936 S.W.2d 104 (Mo banc 1996).

Punitive damages are not warranted under Missouri law solely by identifying meeting minutes, generic injury reports, and studies recommending design improvements that may or

[7] Although Biomet continues to maintain that Indiana law governs Plaintiffs' claim for punitive damages, *see* Dkt. 200 at 1-5, it recognizes that the Court has ruled that Missouri law applies to that claim, *see* Dkt. 293.

[8] Defendants recognize that the Court has bifurcated the trial of the punitive damages claim, and had Plaintiff offered sufficient evidence to to allow for an award ofpunitive damags on the underlying claim, in the second phase plaintiffs could offer evidence concerning Defendants' "state of mind" or financial condition. *See* Dkt. 294. Nevertheless,Plaintiffs have completed the submission of their evidence concerning Defendants' conduct with respect to the design of the M2a Magnum. Because that evidence is and must be the basis for any claim of punitive damages as well, *see State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003), Plaintiffs have "been fully heard" on the underlying causes of action and, in turn, any claim for punitive damages. *See, e.g., Teneyck v. Omni Shoreham Hotel*, 365 F.3d 1139, 1149 (D.C. Cir. 2004) ("[A] party has been 'fully heard' for purposes of Rule 50(a) when the party has submitted all of its evidence on the relevant claim or issue") (citing 9 James Wm. Moore et al., Moore's Federal Practice § 50.20[2] (3d ed.2004)).

may not relate to a plaintiff's injuries or the specific design of the product at issue. *Hancox v. Cottrell, Inc.*, No. 05-0314-CV-W-GAF, 2007 WL 9718030, at * 3 (W.D. Mo. Aug. 9, 2007).

B. Plaintiffs have failed to offer sufficient evidence to permit an award of punitive damages.

Because a claim for punitive damages is not an independent cause of action, but merely a remedy that must be asserted in conjunction with a substantive claim, *see, e.g., Ford v. GACS, Inc*., 265 F.3d 670, 678 (8th Cir. 2001), Plaintiffs must submit sufficient evidence[9] to show, by clear and convincing evidence, that Biomet *designed and tested* the M2a Magnum with "evil motive or reckless indifference to the rights of others." *Burnett v. Griffith*, 769 S.W.2d 780, 789 (Mo. 1989) (quoting Restatement (Second) of Torts § 908(2) (1979)).

First, as set forth above, Plaintiffs failed to submit evidence to support their claims that the specific design of the M2a Magnum was unreasonably dangerous or negligently designed, *see infra* at pp. 4–6, much less clear and convincing evidence of evil intent. No expert offered a critique of the specific M2a Magnum design. At most, Plaintiffs' experts critiqued the entire class of metal-on-metal products, and defendants' decision to use a metal-on-metal articulating surface. No Plaintiffs' expert analyzed the revision rates of the M2a Magnum as compared to the metal-on-plastic articulating surface; and in fact the unrebutted evidence offered by Biomet shows after being on the market 12 years, the revision rates for the M2a Magnum were comparable to all metal-on-poly designs on both the Australian and New Zealand registries. These facts do not come close to meeting the standard for punitive damages.

[9] At the summary judgment stage, the Court stated it was not ***at that time*** "in a position to determine as a matter of law the Plaintiffs cannot make a submissible case for punitive damages." Dkt. 260 at 3. Now that Plaintiffs have submitted their case in support of their strict liability and negligent design claims, it is clear that skepticism about any claim for punitive damages was fully justified.

Moreover, evidence of Biomet conduct unrelated to the company's design of the M2a Magnum cannot *constitutionally* support a claim for punitive damages. The United States Supreme Court has held that a defendant's acts unrelated to those that injured the plaintiff cannot ground a claim for punitive damages. *See State Farm Mutual Auto Insurance v. Campbell*, 538 U.S. 408, 422–23 (2003); Aug. 6, 2020 Tr. at 30:12-31:6.

In the face of this undisputed evidence, Plaintiffs cannot coax the thin testimony of their experts into the proof of Biomet's "evil intent" required under Missouri law. An examination of the evidence Plaintiffs have presented in support of their punitive damage claim, even if viewed in the light most favorable to Plaintiffs, undercuts any argument that they have met the high evidentiary threshold necessary to submit a claim for punitive damages to the jury:

Dr. Kantor does not have the qualifications nor the data that would be necessary for such a determination that Biomet's design for the M2a Magnum evidenced evil intent or reckless disregard for the safety of others. *See* Oct. 8, 2020 Trial Tr. 136:7-9 (never implanted a metal-on-metal hip), *id.* 141:4-11 (never conducted laboratory analysis or clinical studies for the M2a Magnum), 142:7-10 (does not know the ten-year survivorship numbers for any of the M2a line); *id.* 143:13-19 (agrees all implants are not the same); *id.* 145:4-6 (agrees the M2a Magnum does not have "the catastrophic numbers that we are now seeing with other systems"); 184:13-16 (had not reviewed the surgical technique). Kantor's testimony addressed an entire industry and said nothing specific either to the Defendants or to the M2a Magnum.[10] In fact, Judge Miller's

[10] Kantor also testified that he met with the president of Biomet for three hours in 2010 (after Ms. Bayes' implant) to discuss metal-on-metal implants and Dr. Kantor's desire to "contribute to the issues the orthopedic community was facing with regard to the problems of metal-on-metal disease, which was becoming rampant with the increased use of metal-on-metal products the preceding ten years." 10/8/2020 Tr. 51:1-52:3, 211:10-12. Although Kantor did not go on to work for Biomet in this area, *see id.*, the fact that Biomet did not hire Kantor in no way supports Plaintiffs' claim that Biomet had complete indifference to or a conscious disregard for the safety of others.

Daubert ruling in the MDL barred Kantor from offering opinions specifically related to Biomet's design and testing of the M2a Magnum. Doc. 21-5, MDL Expert Order, at 38–39.

Truman's criticisms of Biomet's testing and her focus on frictional torque and clearance do not clearly and convincingly show a sufficient reckless disregard to the safety of others. Ms. Truman testified that she had never performed any testing on frictional torque as it relates to the M2a Magnum, and the M2a Magnum's clearance was "the best you could probably do for a metal-on-metal hip." *See* Oct. 14, 2020 Tr. 141:12-17 (clearance); *id.* 143:3-13 (frictional torque). Indeed, she testified that the clearance for the M2a Magnum "hit more of the sweet spot" and was "in that range that was clinically – had clinically better outcomes." *Id.* at 142:1–11. Truman agreed that all implants wear. *Id.* at 153:10–23. She also agreed that cobalt chrome is the "workhorse material for a lot of orthopedic devices" and is a very good biocompatible material. *Id.* at 153:25-154:6. Truman conceded that Biomet complied with the accepted industry standards for testing. *Id.* 136:18–22.

Plaintiffs used the deposition testimony of Dr. John Cuckler to introduce a 2003 memo that Cuckler authored after returning from a medical conference. In the memo, Cuckler expressed concern over a paper that claimed findings of metal sensitivity in some metal-on-metal implant recipients and recommended asking patients in advance about metal sensitivity. Tr. Ex. 7. Cuckler testified that such hypersensitivity can occur in response to any foreign substance in the human body, Cuckler Dep. at 103:6-7, and that this was a new reaction Cuckler has not encountered before, *id.* at 103:21-24. In the same memo, Cuckler also discussed and attached an excerpt of the MacDonald study (Biomet's ion study) that was presented at the same conference. Tr. Ex. 3. In discussing that study, Cuckler notes that "Metal-metal hip replacements offer several advantages over conventional metal on polyethylene implants, *id.*, and, with respect to

the production of ions in such implants, comments that "significance of these elevated ions however, remains unclear." *Id.* The context and full content of the memo make clear that metal sensitivity from ions was a new issue at the time, and any attempt by Plaintiffs to use the memo to try to paint Biomet as having an "evil intent" in making metal-on-metal implants that had "several advantages" over metal-on poly implants strains and distorts the memo in a way that no reasonable juror could.

In sum, Plaintiffs' evidence fails as a matter of law to meet the high threshold for punitive damages under Missouri law. Even assuming for the sake of argument that Plaintiffs' evidence created a jury question on a claim of product defect or negligence, it could not persuade any reasonable juror that clear and convincing evidence shows that Biomet's conduct "showed complete indifference to or a conscious disregard for the safety of others." *Jone*, 183 S.W.3d at 610. Plaintiffs' punitive damages claim fails as a matter of law for lack of evidence, and the Court should grant Defendants' JMOL on that claim. *See Hancox*, 2007 WL 9718030, at *3 (granting motion for summary judgment on punitive damage claim); *Jone*, 183 S.W.3d at 610–11 (affirming summary judgment on punitive damage claim).

CONCLUSION

For the reasons set forth above, Biomet urges the Court to grant its motion and to order judgment as a matter of law in its favor on all of Plaintiffs' remaining claims against it.

Respectfully submitted by:

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CERTIFICATE OF SERVICE

I certify that on October 20, 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the all counsel of record registered to receive electronic Notices of Electronic Filing generated by CM/ECF.

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